

# **Exhibit B**

# ***MEDICAL MANAGEMENT OF TRANSGENDER INMATES***

**Federal Bureau of Prisons  
Clinical Guidance**

***DECEMBER 2016***

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## 1. PURPOSE

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The Federal Bureau of Prisons (BOP) Clinical Guidance for *Medical Management of Transgender Inmates* provides recommendations for the medical management and treatment of transgender federal inmates, referred to in these guidelines as *individual(s) or person(s)*.

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## 2. INTRODUCTION

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### NATURAL HISTORY

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**TRANSGENDER (TG)** individuals are those whose gender identity is different from their biological sex. **GENDER DYSPHORIA (GD)**, previously known as **GENDER IDENTITY DISORDER (GID)**, is the *discomfort or distress* caused by a discrepancy between a person's **GENDER IDENTITY** and that person's **GENDER** assigned at birth. Not all **TG** will be diagnosed with **GD**, and a diagnosis of **GD** is not required for access to services. Data indicate significantly higher rates of mental health morbidity among **TG** individuals, compared with the general population—particularly anxiety, depression, and suicidality. Present-day treatment approaches involve supporting individuals in modifying their lifestyle—and if indicated, physically modifying their body—to better match the gender with which they psychologically identify.

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### DEFINITIONS

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**ASEXUAL:** Refers to a person not attracted to either sex.

**BISEXUAL:** Refers to a person attracted to both sexes.

**BOP TRANSGENDER CLINICAL CARE TEAM (TCCT):** A multidisciplinary group of BOP personnel with **TG** subject matter expertise. The team provides assistance to institution staff and develops clinical treatment recommendations for the BOP **TG** population.

**BOP TRANSGENDER EXECUTIVE COUNCIL (TEC):** A group of BOP management personnel who mitigate executive level non-clinical issues. This group provides oversight to the **BOP TCCT**.

**FEMALE-TO-MALE (FTM):** Refers to a biological female who identifies as, or desires to be, a member of the male gender. The term *transgender male*, or *trans male* for short, is used to refer to the **GENDER IDENTITY** of a person who is **FTM**. (See the definition of **TRANSGENDER** below.)

**GAY:** Refers to a person who is romantically or sexually attracted to persons of the same gender. The term is mostly used to describe males. (See the definition of **LESBIAN** below.)

**GENDER:** A biopsychosocial construct used to classify a person as male, female, both, or neither. **GENDER** encompasses all relational aspects of social identity, psychological identity, and human behavior.

**GENDER-AFFIRMING HORMONES:** Hormonal therapy utilized to facilitate biological change(s) during **TRANSITION**. The term **CROSS-SEX HORMONES** is often utilized in the medical literature.

**GENDER CONFORMITY:** Behavior and appearance that adheres to the social expectations of a particular **GENDER**. (See the definition of **GENDER NONCONFORMITY** below.)

**GENDER DYSPHORIA (GD):** The condition of feeling that one's emotional and psychological identity as male or female is different from one's biological sex. By definition, **GD** implies that there is a state of distress or anxiety directly related to this conflict. In the *Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5)*, released in May 2013, people whose assigned sex at birth is contrary to the one they identify with *and* who are experiencing a state of distress should be diagnosed with **GD**. This diagnosis is a revision of the criteria in the *DSM-IV* for **GENDER IDENTITY DISORDER**, and is intended to better characterize the experiences of affected individuals.

➔ *Individuals identifying as TG do not necessarily have GD.*

**GENDER EXPRESSION:** Includes mannerisms, clothing, hair style, and choice of activities that individuals use to express their **GENDER IDENTITY**.

**GENDER IDENTITY:** Individuals' own sense of their **GENDER**, which they may choose to communicate to others by means of **GENDER EXPRESSION**.

**GENDER IDENTITY DISORDER (GID):** Strong, persistent feelings of identification with the opposite gender and discomfort with one's own assigned sex.

➔ *The DSM-5 no longer uses this term. See the definition of GENDER DYSPHORIA above.*

**GENDER NONCONFORMITY:** Behavior or appearance that does not match the societal roles or expectations for one's assigned **GENDER**.

**HETEROSEXUAL:** Refers to a person attracted to the opposite gender.

**HOMOSEXUAL:** Refers to a person attracted to the same gender.

**INTERSEX:** Refers to a person whose sexual/reproductive anatomy or chromosomal pattern does not seem to fit the typical biological definition of male or female.

**LESBIAN:** Refers to a female who is attracted to other females.

**MALE-TO-FEMALE (MTF):** Refers to a biological male who identifies as, or desires to be, a member of the female gender. The term *transgender female*, or *trans female* for short, is used to refer to the **GENDER IDENTITY** of a person who is **MTF**. (See the definition of **TRANSGENDER** below.)

**REAL-LIFE EXPERIENCE (RLE):** When individuals live as the **GENDER** with which they identify.

**SEX:** A biological classification based on chromosomal composition, reproductive anatomy (primary sex characteristics), and phenotypic characteristics (secondary sex characteristics) that develop during pubertal maturation.

**SEX REASSIGNMENT SURGERY:** The surgical component of an individual's **TRANSITION**; also referred to as **GENDER-AFFIRMING SURGERY**.

**SEXUAL ORIENTATION:** The direction of one's sexual interest toward members of the same sex, the opposite sex, both, or neither.

**TRANSGENDER (TG):** A general term used for individuals whose **GENDER IDENTITY** does not conform to the typical expectations associated with the gender they were assigned at birth.

- While the term is often used synonymously with the term **GD**, being **TG** does not necessarily imply anxiety or distress about one's gender not matching one's assigned sex.
- The term **TRANSGENDER** also does *not* imply a particular **SEXUAL ORIENTATION**.
- A **MALE-TO-FEMALE (MtF) TRANSGENDER** person refers to a biological male who identifies as, or desires to be, a member of the female gender; a **FEMALE-TO-MALE (FtM) TRANSGENDER** person refers to a biological female who identifies as, or desires to be, a member of the male gender.

**TRANSITION:** The period during which **TG** individuals change their physical, social, and legal characteristics to the gender with which they identify. **TRANSITION** may also be regarded as an ongoing process of physical change and psychological adaptation.

## SPECIAL CONSIDERATIONS

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### STIGMA

Stigma and prior negative experiences in institutions can impede transition services, and/or diagnosis and treatment of **GD**.

### SUICIDALITY

Transgender adults with **GD** are at an increased risk of suicidal ideation and suicide prior to initiation of their gender transition, regardless of the clinical endpoint of their **TRANSITION**—whether that endpoint is living as the psychologically identified gender, hormone therapy, cosmetic treatments, breast augmentation/removal, and/or sex reassignment surgery. For many individuals, the risk of suicide may decrease after receiving the appropriate, individual treatment.

### COMORBID CONDITIONS

- The most common comorbid conditions seen in **TG** adults with **GD** are anxiety and depression.
  - Epidemiologic studies indicate a higher prevalence of HIV in the **TG** populations, specifically among **MtF** persons.
- ➔ See CDC, *HIV Among Transgender People*, #13 in the [References](#) section.

### GENERAL INTERACTIONS WITH TRANSGENDER INDIVIDUALS

Respect and trust are essential to a clinician-client (physician-patient) relationship. Respectful language and terms should always be used when discussing or referring to all individuals regardless of gender. Once an individual has identified as **TG**, use of pronouns or salutations preferred by the **TG** individual is appropriate, especially for those inmates with a Case Management Activity (CMA) Sentry assignment of **TRANSGENDER** (either TRN M2F or TRN F2M). This practice is more likely to facilitate a cooperative relationship between the **TG** individual and others, and generally reduces the stress of gender transition.

- ➔ Please note that this informal approach is distinct from a legal name change while in BOP custody; a legal name change must conform to the policy requirements in the *Correctional Systems manual*, currently Program Statement 5800.15 (or the most recent version).

**MULTIDISCIPLINARY TREATMENT APPROACH**

A multidisciplinary approach is recommended for managing issues associated with the incarceration of **TG** individuals, including the provision of medical treatment when indicated. Institutional staff training programs should consider incorporating Continuing Medical Education on the clinical care of **TG** individuals.

The BOP offers **TRAUMA-INFORMED CORRECTIONAL CARE (TICC)**, which incorporates an understanding that inmate attitudes, behaviors, and concerns are likely to be affected by prior traumatic experiences. **TICC** includes both training and treatment programs, emphasizes the recognition of trauma in all forms, and incorporates the principle that all staff may have a role in reducing its impact. Subject matter experts within the BOP are available to assist providers and other staff working with **TG** inmates.

**HOUSING ASSIGNMENTS, PROGRAM ASSIGNMENTS, AND PAT SEARCHES**

- ➔ Refer to the current version of *BOP Program Statement 5324.11, Sexually Abusive Behavior Prevention and Intervention Program*.
- ➔ Refer also to the *Transgender Offender Manual Program Statement*.

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**3. INTAKE SCREENING REGULATIONS**


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Prison Rape Elimination Act (PREA) regulations, incorporated into *BOP Program Statement 5324.11, Sexually Abusive Behavior Prevention and Intervention Program*, state that the intake screening shall consider, at a minimum, the following criteria to assess individuals for risk of sexual victimization—whether the individual is known or perceived to be gay, lesbian, bisexual, **TG**, intersex, or gender nonconforming.

- ➔ See **28 C.F.R. § 115.41 (d)**.

Individuals may not be disciplined for refusing to answer, or for not disclosing complete information in response to, questions about being gay, lesbian, bisexual, **TG**, intersex, or gender nonconforming.

- ➔ See **28 C.F.R. § 115.41 (h)**.

Staff shall not search or physically examine any inmate, to include a **TG** or intersex individual, for the sole purpose of determining the individual's genital status. If the individual's genital status is unknown, and as appropriate, it may be determined during conversations with the individual, by reviewing medical records, or, if necessary, learning that information as part of a broader medical examination conducted in private by a medical provider.

- ➔ See **28 C.F.R. § 115.15 (e)**. *This provision does not limit searches of individuals to ensure the safe and orderly running of the institution.*



## 4. TRANSGENDER-IDENTIFYING CHARACTERISTICS

Transgender status is based on an individual's self-report of identifying characteristics. When an individual self-identifies as **TG**—or requests referral or evaluation for treatment—a medical and/or mental health evaluation is conducted according to policy, and as clinically appropriate to fully evaluate the individual's treatment needs.

The following criteria may be useful in identifying a person's status as **TG**:

***A persistent and marked difference between a person's preferred gender and their biologic or natal sex, which may be experienced as or accompanied by:***

- ▶ ***Strong feelings about primary or secondary sex characteristics;***
- ▶ ***Strong feelings about being treated as or becoming another gender; or***
- ▶ ***Belief that one's actions, feelings, or mannerisms are more characteristic of another gender.***

## ELECTRONIC MEDICAL RECORD (EMR) CODES

For purposes of providing appropriate medical treatment and management, all individuals who identify as **TG**—whether or not they are receiving hormone treatment—need to have the appropriate code for transgender individuals entered into the EMR health problem list, as listed below in *Table 1*.

**TABLE 1. EMR CODES FOR TRANSGENDER INDIVIDUALS**

BOP Transgender Determination	EMR Codes <sup>1,2</sup>	Corresponding Sentry CMA Codes
Transgender, male to female	F64.0f	TRN M2F
Transgender, female to male	F64.0m	TRN F2M
<sup>1</sup> <i>EMR Transgender codes are solely for the use of clinical providers during the course of medical intervention and treatment. The respective codes are to be applied to inmates whose transgender identity has been confirmed and for whom medical treatment is appropriate, as described in the Transgender Offender Manual Program Statement and in this BOP Clinical Guidance.</i>		
<sup>2</sup> <i>If an individual has undergone sex reassignment surgery, use code Z87.890 (Personal History of Sex Reassignment) along with the appropriate F64 code above.</i>		

**IMPORTANCE OF CODING TG INDIVIDUALS:** Coding of the **TG** determination status is imperative for accurate individual records to ensure all individuals are receiving appropriate care and management. All BOP individuals who self-identify as **TG**, or are identified by history or current presentation as **TG**, need to be assessed by the appropriate psychology and/or health service staff in a timely fashion. Treatment and management of the **TG** individual are individualized and proceed from a thoughtful assessment, consideration of the individual's presentation and preferences, and attention to safety and security needs of the individual. This is all performed within the context of ensuring the safe and orderly operation of the institution.

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## 5. ASSESSMENT AND MANAGEMENT OF THE TG INDIVIDUAL – A MULTIDISCIPLINARY APPROACH

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Healthcare for **TG** individuals requires a multidisciplinary approach. The following process is recommended for transgender individuals (especially those newly identifying as **TG**) seeking medical intervention to assist with gender transition needs:

- **FIRST STEP – MENTAL HEALTH ASSESSMENT:** The first step in the process is for the individual to be seen by psychology staff for a comprehensive mental health assessment. Psychology staff will be able to confirm an individual's **TG** identity, diagnose mental health conditions based on DSM criteria, address the inmate's mental health concerns, and provide individualized counseling support and other interventions as appropriate.  
➔ See [Section 6. Mental Health Assessment](#).
- **SECOND STEP – MEDICAL ASSESSMENT:** The second step is for psychology staff to refer the individual for an evaluation by a medical provider if the patient desires medical intervention. If appropriate, the medical provider can initiate hormone therapy after the risks and benefits have been discussed with the individual, and the **BOP TCCT** has been consulted. Pharmacists may also play a role in treatment by counseling individuals on medications and recommending appropriate medication selection and/or lab monitoring to the medical provider. Psychiatrists may be consulted in cases of significant mental health challenges requiring medical intervention.  
➔ See [Section 7. Medical Assessment](#).
- **THIRD STEP – INDIVIDUALIZED TREATMENT:** In many cases, treatment is designed to reduce characteristics of the natal sex and induce those of the identified gender, allowing individuals to project their **GENDER IDENTITY**. The treatment and management of the **TG** individual requires individualized care guided by treatment goals to allow for successful **TRANSITION** through education, counseling, real-life experience, medical evaluation, hormone treatment, and in some cases, sex reassignment surgery.  
➔ See [Section 8. Stepwise Approach to Medical and Mental Health Treatment of TG Individuals](#).

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### GENDER DYSPHORIA (GD) CRITERIA

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Individuals identifying as transgender do not necessarily have **GD**. Although data are insufficient to know the prevalence rates of **GD** in the transgender population, anecdotally many clinicians report that most transgender individuals experience some degree of dysphoria in the absence of treatment. Because untreated or under-treated **GD** is associated with increased morbidity and mortality, screening for **GD** in **TG** individuals is essential. Without treatment, this population may experience higher rates of depression, anxiety, and suicidality. Treatment modalities may include psychotherapy, supportive changes in gender expression and role, hormone therapy, and surgical therapy. Where indicated, hormonal interventions may improve **GD**, mental health comorbidities, and overall quality of life.

**The DSM-5 criteria may be used to make the diagnosis of GD, and include two major categories:**

**(1)** Gender incongruence, i.e. a significant difference between a person's experienced or expressed gender and their assigned gender, and **(2)** significant distress or dysfunction that results from the gender incongruence. Readers are referred to the DSM-5 or to the DSM website (subscription required for access to copyrighted material) for the specific DSM-5 criteria.

➔ See DSM-5, #1 in the [References](#) section.

A diagnosis of **GD** will be recorded in the EMR health problem list under the appropriate DSM code (F64.1). Referral to a mental health professional for co-management of **GD** is recommended.

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## 6. MENTAL HEALTH ASSESSMENT

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**Transgender status is based on an individual's self-report. Therefore, the history or subjective component of the evaluation serves as the primary source for identifying a person as TG.** When transgender individuals request mental health services or are referred to Psychology Services, or when medical intervention for **TG** transition is being considered, it is appropriate to conduct a mental health evaluation.

**The mental health assessment typically includes:** **(1)** Obtaining a history of gender identity and screening for **GD**; **(2)** screening for other mental health disorders related to autism, eating, mood, personality, psychosis, and substance use; **(3)** identifying a history of abuse or neglect and any current or past self-harm ideations or attempts; **(4)** performing an assessment of affective, cognitive, and psychosocial functioning, if indicated; **(5)** psychosocial treatment recommendations; and/or **(6)** medical referral, if indicated.

➔ Please also refer to APA, *Guidelines for psychological practice with transgender and gender nonconforming people*, #12 in the [References](#) section.

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## DIAGNOSTIC ASSESSMENT

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Diagnostic assessments are completed in PDS-BEMR under the title Diagnostic and Care Level Formulation and include the following:

- **PRESENTING PROBLEMS/SYMPTOMS:** Outline the individual's concerns, including who made the referral and when.
- **RELEVANT HISTORICAL INFORMATION:** This psychosocial history may include a review of the individual's developmental history (including gender identity), sexual history (including sexual predation or victimization), trauma, mental health history, suicide attempts or self-harm, criminal history, educational experience and progress, family dynamics, peer relations, and social support expected upon release.
- **DIAGNOSTIC FORMULATION:** If applicable, list diagnostic impressions.
- **CARE LEVEL FORMULATION:** Provide a discussion of the individual's ongoing need for mental health services and assign a care level consistent with the individual's needs.

## MENTAL HEALTH TREATMENT CONSIDERATIONS

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The mental health team plays an important role in diagnosing individuals, as well as providing psychotherapy and counseling:

- **INDIVIDUAL'S UNDERSTANDING/EXPECTATIONS OF TREATMENT OPTIONS:** Prior to engaging in treatment, conversations regarding the individual's expectations of outcome are required in order to identify realistic goals.
  - ➔ *A collaborative education session for the inmate, with both psychology and medical services staff, is highly recommended.*
- **PSYCHOTHERAPY:** This is a general term for treating mental health problems by the individual discussing them with a mental health provider. Psychotherapy can be used to learn about and treat an individual's moods, thoughts, and behaviors. It can also be supportive to individuals experiencing distressing thoughts and/or feelings.
- **PSYCHIATRY SERVICES:** Individuals can also be referred to psychiatry services for mental health concerns or medication management of other mental illness in conjunction with **GD**.
  - ➔ *A psychiatry consult is not needed for a diagnosis of GD. The diagnosis may be made by another mental health provider, based on DSM-5 criteria.*

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## 7. MEDICAL ASSESSMENT

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Once Psychology Services has completed the mental health assessment and ascertained the individual's **TG** goals—or otherwise determined that the individual is in need of a medical evaluation—the psychologist will refer the individual to the appropriate Health Services staff for specific medical interventions. A medical assessment should include:

- **REVIEW OF THE MENTAL HEALTH ASSESSMENT**
- **ASSESSMENT OF OVERALL HEALTH**
- **ASSESSMENT OF PREVIOUS TREATMENT** (hormonal therapy, surgery, etc.).
- **CO-OCCURRING MEDICAL DISORDERS:** Given the increased risk for individuals with thrombotic, hepatic, and oncological conditions who undergo hormonal therapy, it is crucial that comorbid conditions be managed appropriately and carefully.
  - ➔ *Please note that comorbidities are not necessarily a contraindication to therapy and must be assessed for each individual. See more about drug risks in [Table 3 \(MTF\)](#) and [Table 4 \(FTM\)](#).*
- **INFORMED CONSENT:** Individuals must be counseled on the risks and long-term effects of hormonal therapy. Use of gender-affirming hormones in the management of **TG** individuals is considered an off-label use and does not currently have FDA approval. Due to the irreversibility of some of the treatment options and the side effects, the individual's informed consent is required before initiating treatment and must be documented within the medical record.
  - ➔ See [Section 12](#), *Patient Education & Informed Consent*.

- **CONTRAINDICATIONS:**

➔ See the Treatment Summary Charts in [Appendix 1a \(MtF\)](#) and [Appendix 1b \(FtM\)](#) for medication-specific contraindications.

**MtF**

- ▶ **ABSOLUTE:** History of estrogen-sensitive cancer (e.g., breast cancer); history of thromboembolic disease (unless provided with concurrent anti-coagulation therapy); history of macroprolactinoma.
- ▶ **RELATIVE:** Liver, kidney, or heart disease/stroke (or risk factors for heart disease such as high cholesterol, diabetes, obesity, smoking); strong family history of breast cancer or thromboembolic disease; gallbladder disease.

**FtM**

- ▶ **ABSOLUTE:** Pregnancy; breast feeding; history of breast cancer (testosterone may have anti-proliferative effects on most, but not all, breast cancers).
- ▶ **RELATIVE:** Androgen-sensitive epilepsy; migraines; sleep apnea; polycythemia (elevated red blood cell count); cardiac failure; renal failure or severe hypertension susceptible to salt retention and fluid overload; significant liver disease; coronary artery disease (CAD) or risk factors for CAD; history of uterine cancer; bleeding disorders (for injected testosterone); significant history of violent behavior.

## 8. STEPWISE APPROACH TO MEDICAL AND MENTAL HEALTH MANAGEMENT OF TG INDIVIDUALS

Table 2 summarizes the step-by-step approaches to medical and mental health management of **TG** individuals in the BOP. It should be noted that ongoing release preparation and BOP Social Worker referral may facilitate a successful return to the community.

➔ See [Section 9, Hormone Treatment](#), [Section 10, Medications for MtF Individuals](#), and [Section 11, Medications for FTM Individuals](#) for more detailed information on medical treatment.

**TABLE 2. STEPWISE APPROACH TO MTF AND FTM MEDICAL AND MENTAL HEALTH MANAGEMENT**

1	Individual identifies as <b>TG</b> and seeks medical intervention to assist with transition; mental health assessment provided (see <a href="#">Section 6</a> ); continuation of counseling by psychology services if indicated; and implementation/initiation of <b>REAL-LIFE EXPERIENCE (RLE)</b> .	
2	Referral to medical provider for medical evaluation; laboratory workup; discussion of realistic expectations of hormonal therapy; and informed consent for hormone treatment. See <a href="#">Section 7</a> .	
3	Discussion with <b>BOP TCCT</b> and psychiatric clinical pharmacist consultant, followed by a non-formulary request submission.	
4	<b>MtF</b>	<b>FtM</b>
	Once non-formulary request has been approved, begin hormonal therapy with anti-androgen (spironolactone first, unless contraindicated) and estrogen (see <a href="#">Appendix 1a</a> for choosing a preparation).  Start low and titrate to appropriate level while using lowest effective dose.  ➔ See <a href="#">Hormone Therapy for MtF</a> in Section 9.	Once non-formulary request has been approved, begin hormonal therapy with testosterone (see <a href="#">Appendix 1b</a> for choosing a preparation).  Start low and titrate to appropriate level while using lowest effective dose.  ➔ See <a href="#">Hormone Therapy for FtM</a> in Section 9.
5	<b>MtF</b>	<b>FtM</b>
	If treatment has reached maximum estrogen dose without seeing desired effects, consider adding another anti-androgen such as finasteride, gonadotropin-releasing hormone (GnRH) agonist, or medroxyprogesterone.  Consult <b>BOP TCCT</b> .	If still experiencing uterine bleeding after first few months of high-dose testosterone therapy, consider adding medroxyprogesterone or a GnRH agonist to suppress menstruation.  Consult <b>BOP TCCT</b> .
6	Evaluation of individual by <b>BOP TCCT</b> for potential appropriateness of surgical intervention upon institution referral.  ➔ See <a href="#">Section 12</a> for general criteria for consideration of surgery.	
7	Surgical intervention.*	

\* For further considerations, please refer to the most recent guidelines from the World Professional Association on Transgender Health (WPATH), the Endocrine Society, and the American Association of Obstetricians and Gynecologists (Committee Opinion), available at: [http://www.wpath.org/site\\_page.cfm?pk\\_association\\_webpage\\_menu=1351](http://www.wpath.org/site_page.cfm?pk_association_webpage_menu=1351).

Cases will be reviewed on a case by case basis by BOP Central Office through a referral from the **BOP TCCT**.

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## 9. HORMONE TREATMENT: ELIGIBILITY, GOALS, OVERVIEW

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**Hormone supplementation is an important part of transitional treatment for many transgender individuals.** Studies demonstrate improvement (in the range of 70–80%) in gender dysphoria, mental health, quality of life, and sexual function, for transgender treatment that included hormone therapy. The goals of hormone treatment are **(1)** to suppress endogenous hormones and physical characteristics of the natal sex and **(2)** to supplement hormones and enhance characteristics of the preferred gender, utilizing the principles of hormone replacement therapy for hypogonadal individuals of the **TG** individual's identified gender.

- The information in this section is in part adapted from VA Pharmacy Benefits Management Services, *Transgender Cross-Sex Hormone Therapy Use*, (#2 in the [References](#) section) and Endocrine Treatment of Transsexual Persons: An Endocrine Society Clinical Practice Guideline (#3 in the [References](#) section).

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### ELIGIBILITY AND READINESS FOR GENDER-AFFIRMING HORMONE THERAPY

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**WPATH CRITERIA:** Current WPATH guidelines identify four eligibility criteria for hormone therapy, but also emphasize the need for individualized treatment plans that may include hormone therapy in selected cases that do not meet all four criteria. The WPATH criteria are as follows:

- (1)** Gender dysphoria that is persistent and documented.
- (2)** Medical and/or mental health conditions, if present, are reasonably well-controlled.
- (3)** Legal age of majority (currently 18 years in all states except Alabama and Nebraska, which use 19 years).
- (4)** Informed consent.

**ENDOCRINE SOCIETY CRITERIA:** As part of their eligibility criteria, the Endocrine Society also includes ICD-10 criteria for transsexualism as an alternate criterion for gender dysphoria, and requires three months of documented real life experience or psychotherapy. The Endocrine Society further describes readiness criteria to include further consolidation of the preferred gender identity and progress in the gender transition, as well as willingness and ability to take hormones as prescribed.

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### HORMONE THERAPY FOR MALE-TO-FEMALE (MTF)

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Feminizing treatment is generally the more complex of the two gender-affirming regimens and consists of either one medication alone or a combination of an anti-androgen and an estrogen, with a potential progestin adjunct. Most clinical studies and guidelines recommend therapy with an anti-androgen and an estrogen, although androgen suppression may be used alone in individuals desiring a more androgynous appearance.

- **Individuals should have realistic expectations of the treatment results, as well as the timeline of when to expect them.** Medical staff should provide enough information on an ongoing basis to help individuals set these realistic expectations. Every case is different, and slow change can lead to frustration. It is important to discuss realistic expectations with the



individual in order to avoid any attempts to self-increase the dosage in hopes of speeding up results.

- ▶ Within the first six months of treatment, changes may be seen in body fat redistribution, loss of muscle mass, breast growth, testicular atrophy, decreased erections, decreased sperm production, and a slowing of body/facial hair growth.
- ▶ The maximum effect of treatment may not be seen for more than two years.
- ▶ Treatment does not provide voice alteration, and training to feminize the voice with a speech pathologist may be indicated, based on consultation with the **BOP TCCT**.
- Most treatment results are reversible upon cessation of treatment, but breast growth is permanent and infertility may be irreversible.
- Goal levels of treatment are serum estradiol <200 pg/ml (premenopausal level) and testosterone <55 ng/dl. Serum estradiol levels should not exceed those of a premenopausal female, but doses used to achieve an adequate level may be significantly higher than those used in hormone replacement therapy in menopausal women.
  - ▶ It is important to note that there are individuals who do not require estradiol as part of their hormonal therapy regimen and do well on an anti-androgen therapy alone. There are others who require very little estrogen to obtain desired body characteristics and adequately treat any presenting dysphoria.
  - ▶ Individuals should uniformly be treated with the lowest effective hormone doses. As previously stated, estradiol levels should not routinely exceed a premenopausal level of 200 pg/ml, but the average individual does not usually require levels near that threshold. The same holds true for testosterone levels. While the goal is <55 ng/dl, there is a subset of individuals who do poorly with levels below 35 ng/dl. The ideal levels for these individuals would be between 35–55 ng/dl.
- ➔ *Dose adjustments, based on the individual's response, are made once hormone levels are in the target range.*

## **HORMONE THERAPY FOR FEMALE-TO-MALE (FTM)**

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Masculinizing treatment is the less complex of the two gender-affirming regimens and consists mainly of testosterone supplementation.

- **The individual's realistic expectations about treatment results and the associated timeline are essential prior to beginning treatment.**
- Within the first six months of treatment, body fat redistribution, an increase in libido, an increase in acne, clitoral enlargement, vaginal atrophy, cessation of menses, and infertility may be evident. Alterations in hair growth, voice depth, and muscle mass may take longer—reaching full effects of treatment in two to five years.
- Uterine bleeding should cease within a few months of high-dose testosterone therapy, but treatments such as gonadotropin-releasing hormone (GnRH) agonists, medroxyprogesterone, and endometrial ablation may be used to stop menses prior to starting testosterone therapy or to decrease estrogen levels.



- Most effects are reversible upon cessation of treatment, but changes in hair, voice depth, and fertility may be irreversible.
- Goal treatment levels are serum estradiol <50 pg/ml and serum total 350–700 ng/dl (male physiologic range; some sources quote a normal reference range of 400–800 ng/dl). If a peak testosterone level is drawn for injectable testosterone, the level should not exceed 1,000 ng/ml. Prior to the ninth month of treatment, total testosterone levels may read high, while free testosterone levels are within the normal range. This may be due to the possibility of high levels of sex hormone binding to globulin in some women.
  - ➔ *Dose adjustments, based on the individual's response, are made once hormone levels are in the target range.*

### HORMONE THERAPY DURING PREGNANCY

Gender-affirming hormone therapy is contraindicated during pregnancy. While therapy may lead to potentially irreversible infertility, it does not function as contraception, and pregnancy is still possible during treatment.

- ➔ *Precautions should be taken to avoid pregnancy during treatment.*

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## 10. MEDICATIONS FOR MTF INDIVIDUALS

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### MTF MEDICATIONS: DRUG CLASSES

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- ➔ See the **MTF Treatment Summary Chart** in [Appendix 1a](#) for summarized information on each of the medication groups below—including dosing, adverse effects, contraindications, interactions, and monitoring.

#### ANTI-ANDROGENS

**Anti-androgens reduce testosterone levels, allowing estrogen therapy to be used in lower doses while still reaching a maximum effect.** Medications with anti-androgen effects include spironolactone, finasteride, GnRH agonists, and progestins.

- **SPIRONOLACTONE** is a potassium-sparing diuretic that directly inhibits testosterone secretion and androgen binding to the androgen receptor. Spironolactone can suppress facial and body hair growth, male pattern baldness, libido, and sexually stimulated erections. It decreases symptoms of benign prostate hypertrophy (BPH) and can lead to modest breast growth.
  - ➔ *The use of spironolactone is contraindicated in renal insufficiency and with a potassium value greater than 5.5 mEq/L. Spironolactone can cause hyperkalemia and hypotension. It is important to monitor potassium levels and blood pressure of individuals taking spironolactone, as stated in [Appendix 1a](#).*
- **FINASTERIDE** inhibits the enzyme responsible for converting testosterone to its potent form. It can be used alone at high doses (5–10 mg/day) in individuals intolerant to spironolactone, or as an adjunct to spironolactone. Effects are similar to those of spironolactone treatment, but spironolactone treatment is considered first line due to observed responses. Finasteride can be used in low doses (1 mg/day) to treat male pattern baldness. Finasteride can reduce BPH symptoms by reducing the size of the prostate.
  - ➔ *Finasteride should not be used when prostate cancer is suspected, due to its ability to lower prostate-specific antigen levels.*

- **GnRH AGONISTS** include goserelin, nafarelin, and leuprolide. These medications suppress pituitary gonadotropin levels and gonadal steroids. They are most often used in adolescents for suppression of puberty, but can be used to decrease testosterone levels and the amount of estrogen needed for **MtF TG** individuals. One advantage of using GnRH agonists in adolescents is that their effects are generally fully reversible. GnRH agonists do not carry the risk of thromboembolic disease.
- **PROGESTINS** are a group of hormones that include medroxyprogesterone. Use of medroxyprogesterone is controversial and not routinely recommended, but it can be used alone in individuals intolerant to other agents, or as an adjunct for individuals receiving maximum estrogen doses without desired effects. Medroxyprogesterone has anti-androgen effects at high doses, but is not more effective than spironolactone. It is purported to aid in breast development at a cellular level, but its effect is mainly on the uterus, and evidence as an effective agent in gender-affirming hormone therapy is lacking.
  - ➔ *Medroxyprogesterone treatment comes with risk of developing mood disorders (depression/irritability), lipid abnormalities, weight gain, and edema. There is also a concern of increased cardiovascular risk.*
- **OTHER ANTI-ANDROGENIC AGENTS** include flutamide and cyproterone acetate, but are not commonly used in the U.S. Cyproterone acetate is widely used in Europe, but is not available in the United States. Flutamide blocks androgen binding, but comes with a risk of hepatotoxicity and has little to no efficacy in reducing testosterone levels.

## ESTROGENS

**Estrogens are used to provide feminization in the form of physical appearance and sexual characteristics.** Effects include development of breasts, redistribution of body fat, softening of the skin, shrinkage of the testes, and testicular atrophy. Many formulations of estrogen are available, including parenteral, transdermal, and oral. Estrogen may have positive health effects more generally, including increased high-density lipoprotein, decreased low-density lipoprotein, and preservation of bone mineral density.

➔ *A list of adverse events and necessary lab monitoring can be found in [Appendix 1a](#).*

- All estrogens come with a risk of thromboembolism, but lower doses and transdermal formulations are considered safer and should be used in populations at higher risk of thromboembolism (>35 years old, smoker, obese). Synthetic estrogens, especially ethinyl estradiol, have been shown to have a higher risk of thromboembolism.
- Intramuscular (IM) injections can cause greater peaks and troughs in estrogen levels, causing more mood issues than oral and transdermal preparations, making oral and transdermal preparations preferable.
- Use of estrogen should be individualized and adjusted regularly, based on serum estradiol levels and individual-specific concerns. Estrogen should be started at low doses and titrated up as needed, based on hormone levels and individual tolerance. If discontinuation is necessary, consider tapering therapy to alleviate mood disturbances.
  - ➔ *Conjugated and synthetic estrogen formulations cannot be measured through serum estradiol concentrations and are no longer recommended for gender-affirming hormone therapy.*

**MTF MEDICATIONS: DRUG EFFECTS TIMELINE**

- ➔ Refer to the Endocrine Society guideline, Table 14, page 3145 (reference 3 in the [References](#) section of this guidance) for specific expectations of feminizing effects of medication therapy.

In general, a person may expect decreased libido and spontaneous erections to occur within one to three months of starting therapy, with a maximum effect in three to six months. Effects that usually develop in the first three to six months of treatment include redistribution of body fat, decrease in muscle mass and strength, softening and decreased oiliness of skin, breast growth, and decreased testicular volume with a maximum effect in one to three years. A decrease in terminal hair growth usually does not occur until six to 12 months into treatment, with a maximum effect not occurring for at least three years or more. The timelines for male sexual dysfunction and decreased sperm production are either variable or unknown. Voice changes do not occur with hormone treatments.

**MTF MEDICATIONS: DRUG RISKS**

Table 3 lists conditions that can be exacerbated by gender-affirming estrogen therapy. See [Appendix 1a](#) for more information on the adverse effects of estrogen therapy and androgen suppression.

**TABLE 3. MEDICAL CONDITIONS EXACERBATED BY GENDER-AFFIRMING ESTROGEN THERAPY (MTF)**

Very high risk of serious adverse outcomes:	
<ul style="list-style-type: none"> <li>Thromboembolic disease</li> </ul>	
Moderate to high risk of adverse outcomes:	
<ul style="list-style-type: none"> <li>Macroprolactinoma</li> <li>Breast cancer</li> <li>Severe liver dysfunction (transaminases &gt;3x upper limit of normal)</li> </ul>	<ul style="list-style-type: none"> <li>Coronary artery disease</li> <li>Cerebrovascular disease</li> <li>Severe migraine headaches</li> </ul>

**MTF MEDICATIONS: MONITORING**

Gender-affirming hormone therapy has the same risks associated with hormone replacement therapy in biological males and females. Appropriate monitoring is crucial. Weight, blood pressure, physical exams, risk factors, medications, complete blood counts, renal and liver function, and lipid and glucose metabolism should be monitored for all **TG** individuals receiving gender-affirming hormone therapy.

- Clinical and laboratory monitoring is appropriate every three months during the first year, and then once or twice yearly thereafter, except as noted.
  - ➔ Monitor for development of feminine characteristics, for target blood levels, and for adverse effects of medication and other treatment.
- Cardiovascular risk assessment is recommended periodically for all patients treated with hormones in accordance with established guidelines and BOP guidance when available.
  - ➔ Specific parameters that need to be monitored include weight and body mass index, blood pressure, lipids, and blood sugar/glycohemoglobin levels, in accordance with established guidelines.

- Serum testosterone and estradiol levels are obtained before starting those respective medications, and then every three months while on treatment.
  - ➔ *Target levels are < 55 ng/dl for testosterone and < 200 pg/ml for estradiol. Higher levels of testosterone indicate inadequate suppression; higher levels of estradiol are associated with increased risks for thromboembolic disease, liver dysfunction, and development of hypertension.*
- Serum electrolytes, most importantly potassium, and renal function are obtained prior to starting spironolactone, every three months during the first year of treatment, periodically thereafter, or more frequently with increases in dosage or as clinically indicated.
  - ➔ *Dose adjustment or discontinuation of spironolactone is recommended for elevated potassium levels or serum creatinine > 4 mg/dL.*
- Screening for colon, and prostate cancer is recommended in accordance with established guidelines and BOP guidance when available.
- Breast cancer screening guidelines for women are followed for **MtF TG** individuals treated with hormone therapy.
- Screening for osteoporosis with a DEXA scan may be appropriate in some cases.
  - ➔ *In the absence of sufficient data to formulate evidence-based guidelines, it is considered appropriate to screen those who are at least five years post-gonadectomy, those who are 50 to 65 years old and have risk factors for osteoporosis, and all those who are 65 years or older.*
  - ➔ *Bone density measurements for transgender women (MtF) are compared with standards for biological females.*
- Baseline and periodic monitoring of liver enzymes and prolactin levels may be appropriate in those treated with estradiol but there is insufficient data available to make a specific recommendation.

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## 11. MEDICATIONS FOR FTM INDIVIDUALS

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### DRUG CLASSES AND MEDICATION INFORMATION

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- ➔ See the **FrMTreatment Summary Chart** in [Appendix 1b](#) for a full list of the different formulations of testosterone—including summarized information on dosing, adverse effects, contraindications, interactions, and monitoring.

#### TESTOSTERONE

Androgen supplementation is used to induce male sex characteristics, including cessation of menses, voice changes, increased facial/body hair growth, increased muscle mass, and clitoral enlargement. Other effects include increased libido and energy.

- Several formulations are available, ranging from IM injections to transdermal patches and gels. The IM injections release slowly from the muscle, but may induce cyclical side effects that coincide with varying plasma concentrations. To avoid these effects, transdermal preparations can be used; alternatively, for testosterone cypionate and enanthate, a lower dose of IM testosterone can be given once-weekly (instead of every two or more weeks).
- Transdermal patches may take longer than IM doses to reach adequate levels. As a result, testosterone levels should be checked after completing at least one week of therapy with a patch. Precautions should be taken to avoid unintentional exposure.

- While oral formulations are available, they are not used, due to extensive liver metabolism and the associated potential for hepatic complications.
- Androgen use should be individualized and adjusted based on serum testosterone levels, tolerance, and efficacy. As with estrogen, dosing should start low and be titrated up to an appropriate level while keeping the dose as low as possible to minimize side effects.
- Ovulation may still be possible even when undergoing long-term testosterone therapy.
  - ➔ Measures should be taken to avoid pregnancy in those undergoing hormonal therapy.

**Due to the classification of all testosterone preparations as DEA-controlled substances and their associated risk of potential abuse and/or diversion, transdermal patches or gels should be avoided in the correctional environment, if possible.**

➔ **INJECTABLE TESTOSTERONE is the preferred formulation in the correctional environment.**

### PROGESTINS AND GnRH AGONISTS

Medroxyprogesterone and GnRH agonists are not typically used, but may be beneficial in individuals wishing to cease menstruation and decrease estrogen levels prior to testosterone treatment. These medications may also have a use in individuals receiving high-dose testosterone therapy who still experience uterine bleeding after the first few months of treatment.

➔ See [Appendix 1a](#) and [Appendix 1b](#) for information on Medroxyprogesterone and GnRH agonists.

### DRUG EFFECT TIMELINE FOR FTM MEDICATIONS

➔ Refer to the Endocrine Society guideline, Table 13, page 3145 (reference 3 in the [References](#) section of this guidance) for specific expectations of masculinizing effects of medication therapy.

In general, a person may expect the following to occur:

- Effects that develop within the first six months of treatment include increased skin oiliness and acne, fat redistribution, cessation of menses, clitoral enlargement, and vaginal atrophy, with onset within the first three months. Maximum effect usually occurs in one to two years, but may take up to five years in some cases.
- Effects that develop in the six-to-12 month time frame include increased facial and body hair, scalp hair loss, increased muscle mass and strength, and deepening of the voice, with maximum effect often occurring in one to two years.

### FTM MEDICATIONS: DRUG RISKS

Table 4 lists conditions that can be exacerbated by gender-affirming testosterone therapy. See [Appendix 1b](#) for more information on the adverse effects of testosterone therapy.

**TABLE 4. MEDICAL CONDITIONS EXACERBATED BY GENDER-AFFIRMING TESTOSTERONE THERAPY (FTM)**

Very High Risk of Serious Adverse Outcomes	Moderate-to-High Risk of Adverse Outcomes
<ul style="list-style-type: none"> <li>• Breast or uterine cancer</li> <li>• Erythrocytosis (hematocrit &gt;50%)</li> </ul>	<ul style="list-style-type: none"> <li>• Severe liver dysfunction (transaminases &gt;3x upper limit of normal)</li> </ul>

**FTM MEDICATIONS: MONITORING**

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Gender-affirming hormone therapy has the same risks associated with hormone replacement therapy in biological males and females. Some of the adverse effects experienced with chronic testosterone therapy are erythrocytosis, liver dysfunction, hypertension, excessive weight gain, salt retention, lipid changes, excessive or cystic acne, and adverse psychological changes. Appropriate monitoring is crucial. Weight, blood pressure, physical exams, risk factors, medications, complete blood counts, renal and liver function, and lipid and glucose metabolism should be monitored for all **TG** individuals receiving gender-affirming hormone therapy.

- Clinical and laboratory monitoring is appropriate prior to starting treatment, every three months during the first year, and then once or twice yearly thereafter, except as noted.
  - ➔ *Monitor for development of masculine characteristics, for target blood levels, and for adverse effects of medication and other treatments.*
- Cardiovascular risk assessment is recommended periodically for all patients treated with hormones, in accordance with established guidelines and BOP guidance when available.
  - ➔ *Specific parameters that need to be monitored include weight and body mass index, blood pressure, lipids, and blood sugar/glycohemoglobin levels.*
- A pregnancy test is obtained prior to starting treatment for all biological females with child bearing potential.
- Serum testosterone levels are obtained before starting treatment with testosterone, and then every three months while on treatment.
  - ➔ *Target testosterone levels are 350–700 ng/d. Higher levels may be associated with increased risk of side effects and complications.*
  - ➔ *Timing of the testosterone level is determined by the route of administration. Trough testosterone levels are obtained prior to the next dose of **injectable** testosterone. Testosterone levels are recommended three to five hours after an **oral** dose, and any time after one week of therapy on **topical** testosterone.*
- Serum estradiol levels are obtained before starting hormone therapy, and then every three months while on treatment until estradiol levels are < 50 pg/ml and cessation of menses has been six months.
- A complete blood count (CBC) and liver panel are obtained prior to starting hormone therapy, every three months during the first year of treatment, once or twice yearly thereafter, or more frequently as clinically indicated.
  - ➔ *Dose adjustment or discontinuation of testosterone is indicated if the hematocrit is > 54%.*
- Screening for colon cancer is recommended in accordance with established guidelines and BOP guidance when available.
- Breast cancer screening guidelines for women are followed for **FTM TG** individuals treated with hormone therapy and who have not had mastectomies.
- Cervical cancer screening is performed annually in those who are treated with hormone therapy and have cervical tissue (i.e., no hysterectomy).

*(List continues on next page.)*



- Screening for osteoporosis with a DEXA scan may be appropriate in some cases.
  - ➔ *In the absence of sufficient data to formulate evidence-based guidelines, it is considered appropriate to assess bone mineral density prior to starting treatment in those with risk factors for osteoporosis, those who are at least five years status post-gonadectomy, and all those who are 60 to 65 years or older.*
  - ➔ *Bone density measurements for transgender men are compared with standards for biological males.*

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## 12. GENDER-AFFIRMING (A.K.A. SEX REASSIGNMENT) SURGERY

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Although individuals may live successfully as transgender persons without surgery, gender-affirming surgery may be appropriate for some and is considered on a case-by-case basis.

**CRITERIA:** In addition to the eligibility and readiness criteria for hormone therapy, general criteria for consideration of surgery include at least 12 months of successful use of hormone therapy, participation in psychotherapy as clinically indicated, full-time real life experience in their preferred gender, and consolidation of gender identity. The inmate must request consideration for and demonstrate via informed consent a practical understanding of gender-affirming surgery including, but not limited to, permanence, potential complications, and short- and long-term treatment plans.

Requests for surgery are submitted to the **BOP TCCT** for initial review and recommendation to the Medical Director, who is the approving authority. Each referral should include comprehensive medical and mental health summaries, a comprehensive psychosocial assessment (preferably by a licensed clinical social worker), and a criminal history and institutional adjustment report.

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## 13. PATIENT EDUCATION & INFORMED CONSENT

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**Patient education and informed consent are crucial to the treatment process.** Sample consent and counseling documents can be found in [Appendix 2](#) and [Appendix 3](#). Psychology and medical staff should allow individuals to read the appropriate consent forms, as well as discuss the forms with the individuals to ensure that they understand them thoroughly. Informed consent must be documented within the electronic medical record.

- ➔ See [Section 7](#), Medical Assessment and [Section 8](#), Stepwise Approach to Medical and Mental Health Management of TG Individuals for more information.

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**APPENDIX 1A. TREATMENT SUMMARY CHART FOR MTF THERAPY**

★ GOAL LEVELS FOR MTF: SERUM ESTRADIOL <200 PG/ML AND SERUM TESTOSTERONE <55 NG/DL ★						
Anti-Androgen Drugs	Dose	Mode of Action	Adverse Effects	Contraindications	Interactions	Notes/Monitoring
<b>SPIRONOLACTONE</b>	<b>Starting:</b> 25–50 mg BID <b>Typical:</b> 50 mg BID <b>Max:</b> 200 mg BID	Potassium-sparing antihypertensive that directly inhibits testosterone secretion and androgen binding to the androgen receptor	<ul style="list-style-type: none"> <li>• Mild diuretic</li> <li>• Hyperkalemia</li> <li>• Excretion of sodium, calcium, and chloride</li> <li>• Decreased libido</li> </ul>	<ul style="list-style-type: none"> <li>• Renal insufficiency</li> <li>• Potassium &gt;5.5 mmol/L</li> <li>• Avoid after orchiectomy</li> </ul>	<ul style="list-style-type: none"> <li>• Digoxin</li> <li>• ACE inhibitors</li> <li>• ARBs</li> <li>• Potassium-sparing diuretics</li> </ul>	<ul style="list-style-type: none"> <li>• <b>Baseline labs:</b> BMP</li> <li>• <b>Follow-up labs:</b> Serum potassium and renal function in 1 week, monthly for three months, and every three months during first year.</li> <li>• <b>When stable:</b> BMP every 6 to 12 months</li> </ul>
<b>FINASTERIDE</b>	<b>Low:</b> 1 mg daily <b>High:</b> 5–10 mg daily	5α reductase inhibitor, which blocks the conversion of testosterone to the more active 5α dihydrotestosterone	Sexual dysfunction	None pertinent	Antiretrovirals and diltiazem may increase finasteride levels.	<ul style="list-style-type: none"> <li>• <b>High dose:</b> Unable to take spironolactone</li> <li>• <b>Low dose:</b> Treatment of male pattern baldness</li> <li>• Use in combo with spironolactone for rare individuals not achieving desired effects</li> <li>• May be used after orchiectomy if hirsutism or male pattern baldness are present</li> </ul>
APPENDIX 1A, PAGE 1 OF 3 (See <a href="#">APPENDIX 1C</a> for sources and abbreviations.)						

★ GOAL LEVELS FOR MTF: SERUM ESTRADIOL <200 PG/ML AND SERUM TESTOSTERONE <55 NG/DL ★						
Anti-Androgen Drugs	Dose	Mode of Action	Adverse Effects	Contraindications	Interactions	Notes/Monitoring
<b>GNRH AGONISTS:</b> <b>GOSERELIN</b> <b>NAFARELIN</b> <b>LEUPROLIDE</b>	<b>Goserelin:</b> 3.6 mg SQ monthly <b>Nafarelin:</b> 600 µg intranasal daily <b>Leuprolide:</b> 3.75–7.5 mg IM monthly	Neurohormones that block the GnRH receptor, thus blocking release of FSH & LH, leading to highly effective gonadal blockade	<ul style="list-style-type: none"> <li>• Loss of BMD</li> <li>• Hot flashes</li> <li>• Sexual dysfunction</li> <li>• Diarrhea</li> </ul>	None pertinent	None noted	<ul style="list-style-type: none"> <li>• MTF: Use anti-androgen to decrease estrogen use</li> <li>• Fully reversible when used in adolescents to delay puberty</li> </ul>
<b>PROGESTERONE, MEDROXYPROGESTERONE</b>	<b>Starting:</b> 2.5 mg daily <b>Typical:</b> 5–10 mg daily <b>Max:</b> 20 mg daily	<ul style="list-style-type: none"> <li>• Anti-androgen effect at high doses</li> <li>• May help breast development at cellular level</li> </ul>	<ul style="list-style-type: none"> <li>• Increased CV risk</li> <li>• Weight gain</li> <li>• Edema</li> <li>• Mood disorder</li> <li>• Increased facial and body hair</li> </ul>	See below; same contraindications as estrogen.	Antiretrovirals	<ul style="list-style-type: none"> <li>• Not as effective as spironolactone</li> <li>• Adjunct for individuals on maximum estrogen doses with unsatisfactory effects</li> <li>• <b>Monitoring:</b> Same as estrogen; see below</li> </ul>
APPENDIX 1A, PAGE 2 OF 3 (See <a href="#">APPENDIX 1C</a> for sources and abbreviations.)						

★ GOAL LEVELS FOR MTF: SERUM ESTRADIOL <200 PG/ML AND SERUM TESTOSTERONE <55 NG/DL ★					
Estrogen	Dose	Adverse Effects	Contraindications	Notes	Monitoring
ESTRADIOL	<b>Starting:</b> 2–3 mg daily <b>Typical:</b> 4 mg daily <b>Max:</b> 8 mg daily	<b>Common:</b> <ul style="list-style-type: none"><li>Increase in weight, VTE, dyslipidemia, insulin resistance, prolactin levels, edema, N/V, migraine</li><li>Decrease in erections</li><li>Melasma and skin irritation from estradiol patches</li></ul> <b>Less Common:</b> <ul style="list-style-type: none"><li>LFT abnormalities</li><li>Increase in CV events especially in those older than 50 taking progesterone with estrogens</li><li>Increased triglycerides in those taking oral estrogens</li><li>Increased risk of pancreatitis, cholelithiasis, diabetes mellitus, hypertension, and hyperkalemia (in spironolactone users)</li></ul> <b>Rare or plausible but have not been observed:</b> <ul style="list-style-type: none"><li>Liver damage</li><li>Prolactinoma</li><li>Breast cancer (compared with men never exposed to estrogen)</li></ul>	<b>Absolute:</b> <ul style="list-style-type: none"><li>Estrogen-dependent cancer</li></ul> <b>Precautions:</b> <ul style="list-style-type: none"><li>History of VTE</li><li>Coronary artery disease</li><li>Hyperlipidemia</li><li>Diabetes mellitus</li><li>Cigarette smoking</li><li>Highly sedentary lifestyle</li><li>Migraine</li><li>Seizure disorder</li><li>Retinopathy</li><li>Heart failure</li><li>Valvular heart disease</li><li>Family history of estrogen-dependent tumor</li></ul>	<ul style="list-style-type: none"><li><b>Interactions:</b> CYP 3A4, 1A2 inhibitors/inducers</li><li>Transdermal formulations better for older individuals or those with risk factors for VTE</li><li>Stop estrogens two weeks prior to surgery or immobilizing event. Restart after mobilization or one week after surgery</li><li>Consider adding aspirin therapy to those at high risk for VTE</li><li>Individuals who enter the BOP on conjugated estrogen should be switched to a different form of estrogen due to inability to monitor estrogen levels with this preparation</li><li>IM injections cause greater peaks and troughs in estrogen levels making oral and transdermal preparations preferable</li></ul>	<ul style="list-style-type: none"><li><b>Baseline:</b> fasting glucose, lipids, LFTs, prolactin, BMP, BMD if at risk for fracture</li><li><b>Follow-up:</b> glucose and lipids every 2–3 months after starting or dose increase and 1 year after starting</li><li>Check serum testosterone and estradiol every 3 months in first year then 1–2 times per year after for feminization and adverse events</li><li>Optional: LFTs and prolactin after 1 year</li><li>Routine prostate and breast cancer screening</li></ul>
ESTRADIOL VALERATE (PROGYNOVA)	<b>Starting:</b> 2–3 mg daily <b>Typical:</b> 4 mg daily <b>Max:</b> 8 mg daily				
ESTRADIOL SUBLINGUAL (ESTRADIOL MICRONIZED, ESTRACE)	<b>Starting:</b> 0.5–1 mg <b>Typical:</b> 2 mg daily <b>Max:</b> 4 mg daily				
ESTRADIOL VALERATE (DELESTROGEN)	<b>Starting:</b> 20–40 mg IM q2wk <b>Average:</b> 40 mg IM q2wk <b>Max:</b> 40–80 mg IM q2wk <b>Endocrine guidelines:</b> 2–10 mg IM q1wk				
ESTRADIOL CYPIONATE (DEPO-ESTRADIOL)	<b>Starting:</b> 20–40 mg IM q2wk <b>Average:</b> 40 mg IM q2wk <b>Max:</b> 40–80 mg IM q2wk <b>Endocrine guide:</b> 2–10 mg IM q1wk				
ESTRADIOL PATCH (CLIMARA, ESTRADERM, ALORA, VIVELLE-DOT)	<b>Starting:</b> 0.1 mg/24hr <b>Average:</b> 0.2 mg/24hr <b>Max:</b> 0.4 mg/24hr <b>Endocrine guide:</b> 0.1–0.4 mg twice weekly				
ESTRADIOL GEL (DIVIGEL, ELESTRIN, ESTRASORB, ESTROGEL)	Roughly equivalent to patch dosing				
CONJUGATED EQUINE ESTROGENS (PREMARIN)	<b>Starting:</b> 1.25–2.5 mg daily <b>Typical:</b> 5 mg daily <b>Max:</b> 10 mg daily				
APPENDIX 1A, PAGE 3 OF 3 (See <a href="#">APPENDIX 1C</a> for sources and abbreviations.)					

**APPENDIX 1B. TREATMENT SUMMARY CHART FOR FTM THERAPY**

★ GOAL LEVELS FOR FTM: SERUM ESTRADIOL <50 PG/ML AND SERUM TESTOSTERONE 320–1000 NG/DL ★					
Drug	Dose	Adverse Effects	Contraindications	Notes	Monitoring
TESTOSTERONE CYPIONATE (in cottonseed oil) TESTOSTERONE ENANTHATE (in sesame oil)	<b>Starting:</b> 50–100 mg q2wk or 25–50 mg/wk <b>Typical:</b> 200 mg q2wk or 100 mg/wk <b>Max:</b> 400 mg q2wk or 200 mg/wk	<b>Common:</b> <ul style="list-style-type: none"><li>Increase in weight, oily skin, acne, and male pattern baldness</li><li>Vaginal atrophy</li><li>Infertility (possibly irreversible)</li><li>Dyslipidemia</li><li>Mood changes</li><li>Skin irritation with patch</li><li>Risk of exposing partners or children to testosterone with topicals</li></ul> <b>Less Common:</b> <ul style="list-style-type: none"><li>Increase in edema, blood pressure, and aggressiveness</li><li>Erythrocytosis</li><li>Abnormal LFTs</li><li>Sleep apnea</li></ul> <b>Rare or plausible but not observed:</b> <ul style="list-style-type: none"><li>Increased risk of CV disease, breast/ovarian cancer, and endometrial hyperplasia</li></ul>	<b>Absolute:</b> <ul style="list-style-type: none"><li>Pregnancy</li><li>Breast cancer (testosterone may have anti-proliferative effects on most, but not all, breast cancers)</li><li>Breastfeeding</li></ul> <b>Precautions:</b> <ul style="list-style-type: none"><li>Erythrocytosis</li><li>Cardiac, hepatic, renal, or vascular disease with edema or risk of edema</li><li>Sleep apnea or high risk of sleep apnea due to obesity or chronic lung disease</li><li>Dyslipidemia</li></ul>	<ul style="list-style-type: none"><li><b>Interactions:</b> Warfarin, Cyclosporine, Insulin</li><li>Causes drop in blood glucose in DM individuals</li><li>May notice cyclic variation in mood with IM dosing Q 2–4 weeks. Use a lower, more frequent dose, or transdermal</li><li>Transdermal reaches same levels as IM, but in longer timeframe</li><li>Menses typically stop in early months of treatment, but may persist when using transdermals</li></ul> <b>Use in Corrections:</b> <b>Injectable testosterone is the preferred formulation in the correctional environment due to potential risk of abuse and/or diversion. Testosterone is a DEA Controlled Substance</b>	<ul style="list-style-type: none"><li><b>Baseline:</b> CBC, lipids, urine hCG, glucose, &amp; LFTs (if PCOS suspected)</li><li><b>Follow-up:</b> 2–3 months after starting or changing dose CBC, lipids</li><li><b>1 year after start or change:</b> CBC, lipids, LFTs (optional)</li><li>Serum testosterone: every 2–3 months in first year then 1–2 times/year for virilization/AEs</li><li>Serum estradiol: q 2–3 months in first 6 months or until no uterine bleeding for 6 months</li><li><b>When to check specific formulations:</b> <b>IM:</b> Testosterone levels just prior to next dose. Adjust to mid-normal range of 350–700 ng/dl <b>Patch:</b> Testosterone levels after week 1</li><li>Continue screenings for cervical and breast cancer if tissue still present</li></ul>
TESTOSTERONE PATCH Available strengths: 2 mg, 2.5 mg, 4 mg, 5 mg	<b>Starting:</b> 2–2.5 mg/day <b>Typical:</b> 5 mg/day <b>Max:</b> 7.5 mg/day				
TESTOSTERONE GEL (TESTIM 1%, ANDROGEL 1%)	<b>Starting:</b> 2.5 mg every morning <b>Typical:</b> 5 mg every morning <b>Max:</b> 10 mg every morning				
TESTOSTERONE GEL (ANDROGEL 1.62%) TESTOSTERONE SOLUTION (AXIRON axillary solution)	No published or anecdotal experience with these preparations				
MEDROXYPROGESTERONE AND GnRH AGONISTS	See <a href="#">page 2</a> of APPENDIX 1A for dosing and other information.			Used to suppress menstruation if persists after early months of testosterone treatment	
(See <a href="#">APPENDIX 1C</a> for sources and abbreviations.)					

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**APPENDIX 1C. TREATMENT SUMMARY CHARTS: SOURCES AND ABBREVIATIONS**

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**SOURCES FOR TREATMENT SUMMARY CHARTS:** See [References](#) 2, 3, 4, 5, 8, 9, and 10.

**ABBREVIATIONS:**

<b>AEs</b>	Adverse events
<b>ARB</b>	Angiotensin II receptor blocker
<b>BMD</b>	Bone mineral density
<b>BMP</b>	Basic metabolic panel, including glucose, calcium, sodium, potassium, CO <sub>2</sub> , chloride, blood urea nitrogen, and serum creatinine
<b>CBC</b>	Complete blood count
<b>CV</b>	Cardiovascular
<b>DM</b>	Diabetes mellitus
<b>FSH</b>	Follicle-stimulating hormone
<b>FtM</b>	Female-to-male
<b>GnRH</b>	Gonadotropin-releasing hormone
<b>hCG</b>	Human chorionic gonadotropin
<b>IM</b>	Intramuscular
<b>LFT</b>	Liver function test
<b>LH</b>	Luteinizing hormone
<b>MtF</b>	Male-to-female
<b>N/V</b>	Nausea and vomiting
<b>PCOS</b>	Polycystic ovarian syndrome
<b>q</b>	“Every” ( <i>Example: q2wk = every 2 weeks</i> )
<b>SQ</b>	Subcutaneous
<b>VTE</b>	Venous thromboembolism

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## APPENDIX 2. FEMINIZING GENDER-AFFIRMING HORMONE TREATMENT FOR TG PATIENTS – CONSENT AND COUNSELING FORM

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A sample **Consent and Counseling Form** for feminizing gender-affirming hormone treatment for TG patients appears on the next five pages.

**FEMINIZING GENDER-AFFIRMING HORMONE TREATMENT FOR TRANSGENDER PATIENTS**  
**CONSENT AND COUNSELING FORM**

**INSTITUTION NAME:** \_\_\_\_\_

**PATIENT NAME:** \_\_\_\_\_ **ID #:** \_\_\_\_\_

You want to take estrogen and other medications to feminize your body. Once you start these medications, some of them will need to be taken for the rest of your life in order to maintain their effects. Before using these medications, you need to know more about how they might affect you, including possible benefits, side effects, risks, and warning signs. We have listed them here for you. It's important that you understand all of this information before you start. We are happy to answer *any* questions you might have, so please ask!

**WHAT ARE THE DIFFERENT MEDICATIONS THAT CAN HELP TO FEMINIZE YOU?**

Estrogen is the female gender-affirming hormone and there are different types of estrogen that can help you appear more like a woman. There are also medications—called androgen antagonists or anti-androgens or androgen blockers—that can help you appear less like a man. Androgen is the male gender-affirming hormone.

**WARNING — Who Should NOT Take Estrogen?**

**It should NOT be used by anyone who has a history of:**

- An estrogen-dependent cancer
- Blood clots that could or did travel to the lungs

**It should be used WITH CAUTION, and only after a full discussion of risks, by anyone who:**

- Has a strong family history of breast cancer or other cancers that grow faster when estrogens are present
- Has diabetes
- Has eye problems such as retinopathy
- Has heart disease, heart valve problems, or a tendency to have easily clotted blood
- Has hepatitis
- Has high cholesterol
- Has kidney or liver disease
- Has migraines or seizures
- Is obese
- Smokes cigarettes



**Please review and initial each statement to show you understand the benefits, risks, and changes that may occur from taking these medications. At the end of the document, indicate your preference regarding hormone therapy, then sign and date it.**

**FEMINIZING EFFECTS:**

- \_\_\_\_\_ I know that estrogen or anti-androgens—or both—may be prescribed to help me appear less like a man and more like a woman.
- \_\_\_\_\_ I know that it can take several months or longer for the effects to become noticeable. I know that no one can predict how fast—or how much—change will happen.
- \_\_\_\_\_ I know that if I am taking estrogen, I will probably develop breasts.
- I know it can take several years for breasts to get to their full size.
  - I know the breasts will remain, even if I stop taking estrogen.
  - I know I should examine my breasts for irregularities as soon as they start growing. I should also have a clinician examine them every year.
  - I know I might have a milky discharge from my nipples (galactorrhea). If I do, I know I should have it evaluated by my clinician because it could be caused by the estrogen or by something else.
  - I know that no one knows if taking estrogen increases the risk of breast cancer.
- \_\_\_\_\_ I know that the following changes are usually not permanent—they are likely to go away if I stop taking the medicines:
- I know my body hair will become less noticeable and will grow more slowly, but it won't stop completely, even if I take the medicines for years.
  - I know I will probably have less fat on my abdomen and more on my buttocks, hips, and thighs. It will be redistributed to a more female shape, changing from an "apple" shape to more of a "pear" shape.
  - I know that if I already have male pattern baldness, it may slow down, but will probably not stop completely. It is also unlikely that hair that has been lost will grow back.
  - I know I may lose muscle and strength in my upper body.
  - I know my skin may become softer.
- \_\_\_\_\_ I know that my body will make less testosterone. Upon release, this may affect my sex life in different ways and my future ability to cause a pregnancy:
- I know my sperm may no longer reach maturity. This could make me less able to cause a pregnancy. I also know I might never produce mature sperm again, but I know that it's also possible that my sperm could still mature. So, I know that I might get someone pregnant if we have vaginal intercourse, and we don't use birth control. The options for sperm banking have been explained to me.
  - I know my testicles may shrink down to half their size. Even so, I know that I will need regular checkups for them.
  - I know it is likely that my penis won't be hard in the morning as often as it has been before. It is also likely that I will have fewer spontaneous erections.
  - I know I may lose the ability to obtain an erection for intercourse.
  - I know I may have less sex drive.
  - I know this treatment may (but is not assured to) make me permanently unable to make a woman pregnant.

- \_\_\_\_\_ I know that some parts of my body will not change much by using these medicines.
- I know the hair of my beard and moustache may grow more slowly than before. It may become less noticeable, but it will not go away.
  - I know the pitch of my voice will not rise, and my speech patterns will not become more like a woman's.
  - I know my Adam's apple will not shrink.
  - Although these medicines can't make these changes happen, there are other treatments that may be helpful.

**RISKS OF TAKING FEMINIZING MEDICATIONS:**

- \_\_\_\_\_ I know that the side effects and safety of these medicines are not completely known. There may be long-term risks that are not yet known.
- \_\_\_\_\_ I know that I should not to take more medicine than I am prescribed. I know it increases health risks. I know that taking more than I am prescribed won't make changes happen more quickly or more significantly. I know my body can convert extra estrogen into testosterone, and that can slow down or stop my appearing more womanly.
- \_\_\_\_\_ I know these medicines may damage the liver and may lead to liver disease. I know I should be checked for possible liver damage as long as I take them.
- \_\_\_\_\_ I know these medicines cause changes that other people will notice. Some transgender people have experienced harassment, discrimination, and violence because of this. Others have lost the support of loved ones. I know I can reach out to psychology services to help me find support resources. I also know that the BOP does not tolerate harassment, discrimination, and violence in any circumstances. If I feel I am the recipient of any of these actions, I will notify a BOP staff member.

**RISKS OF TAKING ESTROGEN:**

- \_\_\_\_\_ I know that taking estrogen increases the risk of blood clots that can result in:
- Chronic problems with veins in the legs
  - Heart attack
  - Pulmonary embolism (blood clot to the lungs), which may cause permanent lung damage or death
  - Stroke, which may cause permanent brain damage or death
- \_\_\_\_\_ I know that the risk of blood clots is much worse if I smoke cigarettes, especially if I am over 40. I know the danger is so high that I should stop smoking completely if I start taking estrogen and that I should not start to smoke again when I am released from a BOP institution.
- \_\_\_\_\_ I know that taking estrogen can increase the deposits of fat around my internal organs. This can increase my risk for diabetes and heart disease.
- \_\_\_\_\_ I know that taking estrogen can raise my blood pressure. I know that if my blood pressure goes up, my clinician can work with me to try to control it with diet, lifestyle changes, and/or medication.
- \_\_\_\_\_ I know that taking estrogen increases my risk of getting gallstones. I know that I should talk with my clinician if I get severe or long-lasting pain in my abdomen.
- \_\_\_\_\_ I know that estrogen can cause nausea and vomiting. I know that I should talk with my clinician if I have long-lasting nausea or vomiting.

\_\_\_\_\_ I know that estrogen can cause headaches or migraines. I know I should talk with my clinician if I have headaches or migraines often, or if the pain is unusually severe.

\_\_\_\_\_ I know that it is not yet known if taking estrogen increases the risk of prolactinomas. These are non-cancerous tumors of the pituitary gland. I know they are not usually life-threatening, but they can damage vision and cause headaches. I know this possibility needs to be checked periodically by a clinician for at least three years after I start taking estrogen.

\_\_\_\_\_ I know that I am more likely to have dangerous side effects if:

- I smoke.
- I am overweight.
- I am over 40 years old.
- I have a history of blood clots.
- I have a history of high blood pressure.
- My family has a history of breast cancer.

#### **RISKS OF TAKING ANDROGEN ANTAGONISTS:**

\_\_\_\_\_ I know that spironolactone affects the balance of water and salts in the kidneys, which may:

- Increase the amount of urine I produce, making it necessary to urinate more frequently.
- Increase thirst.
- Reduce blood pressure.
- Cause (although rarely) high levels of potassium in the blood, possibly leading to changes in heart rhythms that may be life-threatening.

\_\_\_\_\_ I know that some androgen antagonists make it more difficult to evaluate test results for cancer of the prostate. I know that if I am over 50, I should have my prostate evaluated every year with a prostate-specific antigen test, as applicable.

#### **PREVENTION OF MEDICAL COMPLICATIONS:**

\_\_\_\_\_ I agree to take feminizing medications as prescribed, and I agree to tell my clinician if I have any problems or if I am unhappy with the treatment.

\_\_\_\_\_ I know that the dose and type of medication that is prescribed for me may not be the same as for someone else.

\_\_\_\_\_ I know that I need periodic physical exams and blood tests to check for any side effects.

\_\_\_\_\_ I know that feminization medications can interact with other drugs and medicines—including alcohol, diet supplements, herbs, other hormones, and street drugs—causing complications. I know that I need to prevent complications because they can be life-threatening. That's why I need to be honest with my clinician about whatever else I take or use. I also know that this will not interfere with my getting medical care; I will continue to get medical care here no matter what information I share about what I take.

\_\_\_\_\_ I know that it can be risky for anyone with certain conditions to take feminizing medicines. I agree to be evaluated if my clinician thinks I may have such a condition. Then, we will decide if it's a good idea for me to start or continue using these medications.

\_\_\_\_\_ I know that I should stop taking estrogen two weeks before any surgery or when I may be immobile for a long time. This will lower the risk of getting blood clots. I know that I can start taking estrogen again a week after I'm back to normal or when my clinician says it's okay.

\_\_\_\_\_ I know that using these medicines to appear more womanly is an "off-label" use. I know that this means that using these medicines for this purpose is not approved by the Food and Drug Administration (FDA). I know that the medicine and dose that is recommended for me is based on the judgment and experience of the clinician.

\_\_\_\_\_ I know that I can choose to stop taking these medicines at any time. I know that if I decide to do that, I should do it with the help of my clinician. This will help me make sure there are no negative reactions. I also know that my clinician may suggest that I cut the dose or stop taking it altogether if certain conditions develop. This may happen if the side effects are severe or if there are health risks that cannot be controlled.

**MY SIGNATURE BELOW CONFIRMS THAT:**

- My clinician has talked with me about:
  - ▶ The benefits and risks of taking feminizing medication.
  - ▶ The possible or likely consequences of hormone therapy.
  - ▶ Potential alternative treatments.
- I understand the risks that may be involved.
- I know that the information in this form includes the known effects and risks. I also know that there may be unknown long-term effects or risks.
- I have had enough opportunity to discuss treatment options with my clinician.
- All of my questions have been answered to my satisfaction.
- I believe I know enough to take, refuse, or postpone therapy with feminizing medications.
- I am 18 years old or older.

**BASED ON ALL THIS INFORMATION:**

\_\_\_\_\_ I want to begin taking estrogen.

\_\_\_\_\_ I want to begin taking androgen antagonists (e.g., spironolactone).

\_\_\_\_\_ I do not wish to begin taking feminizing medication at this time.

\_\_\_\_\_  
*Patient's Signature*

\_\_\_\_\_  
*Date*

\_\_\_\_\_  
*Prescribing Physician's Signature*

\_\_\_\_\_  
*Date*

***Your health is important to us. If you have any questions or concerns, please come to sick call and an appointment with your PA/Physician will be made.***

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### **APPENDIX 3. MASCULINIZING GENDER-AFFIRMING HORMONE TREATMENT FOR TG PATIENTS – CONSENT AND COUNSELING FORM**

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A sample ***Consent and Counseling Form*** for masculinizing gender-affirming hormone treatment for **TG** patients appears on the next four pages.

**MASCULINIZING GENDER-AFFIRMING HORMONE TREATMENT FOR TRANSGENDER PATIENTS  
CONSENT AND COUNSELING FORM**

**INSTITUTION NAME:** \_\_\_\_\_

**PATIENT NAME:** \_\_\_\_\_ **ID #:** \_\_\_\_\_

You have expressed a desire to take testosterone to masculinize your body. Before beginning treatment, there are several details about treatment that you need to be familiar with, including the possible advantages, disadvantages, risks, warnings, and alternatives. These topics are covered below. It is important that you understand all of this information before initiating treatment. We are happy to answer *any* questions you might have, so please ask!

**WHAT IS TESTOSTERONE?**

Testosterone is the hormone responsible for male features. It builds muscle, causes the development of facial hair, and is responsible for the deepening of a person's voice during puberty. Testosterone also may increase sex-drive.

**HOW IS TESTOSTERONE TAKEN?**

Testosterone is usually injected every one to four weeks. It is not used as a pill because the body may not absorb it properly, and it can cause liver problems. Some people use skin creams and patches, but these are not used in the correctional environment.

The doses used for injections differ from product to product, and from patient to patient. Doses may range from 100 mg to 400 mg. The injections are administered into a large muscle to slow the release of the hormone. There can be unwanted swings in hormone levels. This can be controlled by changing how often the dose is given, how much of a dose is given, or by changing formulations.

**WARNING — WHO SHOULD NOT TAKE TESTOSTERONE?**

Testosterone should ***not*** be used by anyone who is pregnant or has uncontrolled coronary artery disease. It should be used ***with caution and only after a full discussion of risks*** by anyone who has: acne, family history of heart disease or breast cancer, blood clot history, high levels of cholesterol, liver disease, or high red-blood-cell count. Caution should also be used in obese patients and persons who smoke.

**MONITORING:**

Periodic blood tests to check on the effects of the hormone will be required for treatment. Routine breast exams and pelvic exams with pap tests should be continued, when applicable.

**BENEFITS AND RISKS OF TESTOSTERONE TREATMENT:**

Benefits	Risks
<ul style="list-style-type: none"> <li>• Appearing more like a man:               <ul style="list-style-type: none"> <li>• Larger clitoris*</li> <li>• Coarser skin</li> <li>• Deeper voice*</li> <li>• Increased body hair*</li> <li>• Increased facial hair*</li> <li>• Increased muscle mass</li> <li>• Increased strength</li> <li>• Elimination of menstrual periods</li> </ul> </li> <li>• Increased physical energy</li> <li>• Protection against bone thinning (osteoporosis)</li> </ul> <p><i>*These are permanent changes.</i></p>	<ul style="list-style-type: none"> <li>• Acne (may permanently scar)</li> <li>• Blood clots (thrombophlebitis)</li> <li>• Emotional changes</li> <li>• Headache</li> <li>• High blood pressure (hypertension)</li> <li>• Increased red-blood-cell count</li> <li>• Infertility</li> <li>• Inflamed liver</li> <li>• Interaction with drugs for diabetes and blood thinning — e.g., Coumadin and Warfarin</li> <li>• Male pattern baldness</li> <li>• Increased abdominal fat</li> <li>• Increased risk of heart disease</li> <li>• Swelling of hands, feet, and legs</li> <li>• Weight gain</li> </ul>

**Please review and initial each statement to show that you understand the benefits, risks, and changes that may occur from taking these medications. At the end of the document, indicate your preference regarding hormone therapy, then sign and date it.**

**MASCULINIZING EFFECTS OF TESTOSTERONE:**

\_\_\_\_\_ I know that testosterone may be prescribed to make me appear less like a woman and more like a man.

\_\_\_\_\_ I know that it can take several months or longer for the effects to become noticeable.

\_\_\_\_\_ I know that no one can predict how fast or how much change will take place.

\_\_\_\_\_ ***I know that the changes may not be complete for two to five years after starting testosterone.***

\_\_\_\_\_ ***I know the following changes are likely to be permanent, even if I stop taking testosterone:***

- Bigger clitoris — typically about half an inch to a little more than an inch
- Deeper voice
- Growth of facial hair (moustache and beard)
- Hair loss at the temples and crown of the head and the possibility of becoming completely bald
- More, thicker, and coarser hairs on abdomen, arms, back, chest, and legs

\_\_\_\_\_ I know that the following changes are usually ***not permanent*** and will likely go away if I stop taking testosterone:

- Acne (however, acne scars will be permanent)
- Elimination of menstrual periods (typically stop one to six months after starting testosterone)
- Increased abdominal fat (redistribution of fat to a more masculine shape)
- Decreased fat on buttocks, hips, and thighs
- More muscle mass and strength
- Vaginal dryness

\_\_\_\_\_ I know that the effects of testosterone on fertility are unknown. I have been told that I may or may not be able to get pregnant even if I stop taking testosterone. I know I might still get pregnant even after testosterone stops my menstrual periods. I know my birth control options upon release (if applicable). I know I cannot take testosterone if I am pregnant.

\_\_\_\_\_ I know that some aspects of my body will not be changed:

- Losing some fat may make my breasts appear slightly smaller, but they will not shrink very much.
- Although my voice may deepen, other aspects of the way I speak will not change.

\_\_\_\_\_ I know that there are other treatments that may be helpful to make my breasts smaller or my speech manlier. If I have concerns, I can discuss treatment options with my clinician.

**RISKS OF TESTOSTERONE:**

\_\_\_\_\_ I know that the medical effects and safety of testosterone are not completely known. There may be long-term risks that are not yet known.

\_\_\_\_\_ I know not to take more testosterone than prescribed. I know this would be a risk to my health. I know that taking more testosterone than I am prescribed will not make changes happen more quickly or more significantly. I know that my body can convert extra testosterone into estrogen, which can slow down or reverse the progress of my transition.

- \_\_\_\_\_ I know that testosterone can cause changes that increase my risk of heart disease. I know these changes include:
- Less good cholesterol (HDL), which is needed to protect against heart disease, and more bad cholesterol (LDL), which may increase the risk of heart disease
  - Higher blood pressure
  - Increased deposits of fat around my internal organs
- \_\_\_\_\_ I know that my risk of heart disease is higher if people in my family have had heart disease, if I am overweight, or if I smoke.
- \_\_\_\_\_ I know that I should have periodic heart-health checkups for as long as I take testosterone. I know I must watch my weight and cholesterol levels and have them checked by my clinician.
- \_\_\_\_\_ I know that testosterone can damage the liver and possibly lead to liver disease. I know I should be checked periodically for possible liver damage for as long as I take testosterone.
- \_\_\_\_\_ I know that testosterone can increase my red blood cell count and hemoglobin. I know the increase is usually only to the level that is normal for a man. I know normal levels would have no health risks; however, higher increases can cause problems that can be life-threatening. These problems include stroke and heart attack. As such, I know I need to have periodic blood checks for as long as I take testosterone.
- \_\_\_\_\_ I know that taking testosterone can increase my risk for diabetes. It may decrease my body's response to insulin, cause weight gain, and increase deposits of fat around my internal organs. I know I should have periodic checks of my blood glucose for as long as I take testosterone.
- \_\_\_\_\_ I know that my body can turn testosterone into estrogen. I know that no one knows if this could increase the risk of cancers of the breast, ovaries, or uterus.
- \_\_\_\_\_ I know that taking testosterone can thin the tissue of my cervix and the walls of my vagina. This can lead to tears or abrasions during vaginal intercourse. I know it does not matter if my partner is a woman or a man. This raises my risk of getting a sexually transmitted infection, including HIV. I know I should speak frankly with my provider regarding the best ways to prevent and check for infections. I am aware that sex between inmates, or between inmates and staff, is not permitted within the BOP.
- \_\_\_\_\_ I know that testosterone can give me headaches or migraines. I know it is best to talk with my clinician if I get them frequently or if the pain is unusually severe.
- \_\_\_\_\_ I know that testosterone can cause emotional changes. For example, I could become more irritable, frustrated, or angry. I know my provider can help me find resources to explore and cope with these changes.
- \_\_\_\_\_ I know that testosterone causes changes that other people will notice. Some transgender people have experienced harassment, discrimination, and violence because of this. Others have lost the support of loved ones. I know I can reach out to psychology services to help me find support resources. I also know that in the BOP, harassment, discrimination, and violence are not tolerated under any circumstances. If I feel I am the recipient of any of these actions, I will notify a BOP staff member.



**PREVENTION OF MEDICAL COMPLICATIONS:**

- \_\_\_\_\_ I agree to take testosterone as prescribed, and I agree to tell my clinician if I have any problems or am unhappy with the treatment.
- \_\_\_\_\_ I know that the dose and type of medication prescribed for me may not be the same as it is for someone else.
- \_\_\_\_\_ I know that I need periodic physical exams and blood tests to check for any side effects.
- \_\_\_\_\_ I know that testosterone can interact with other drugs and medicines, including alcohol, diet supplements, herbs, other hormones, and street drugs. This kind of interaction can cause complications. I know that I need to prevent complications because they can be life-threatening. I need to be honest with my clinician about other items I am taking. I also know that this will not interfere with my getting medical care; I will continue to get medical care here no matter what information I share about what I take.
- \_\_\_\_\_ I know that it can be risky for anyone with certain conditions to take testosterone. I agree to be evaluated if my clinician thinks I may have one of these conditions. Then, we will decide if it is a good idea to start or continue using testosterone.
- \_\_\_\_\_ I know that using testosterone to appear more masculine is an "off-label" use. I know this means it is not approved by the Food and Drug Administration (FDA) for this purpose. I know the medicine and dose recommended for me is based on the judgment and experience of the clinician.
- \_\_\_\_\_ I know that I can choose to stop taking testosterone at any time. I know if I decide to stop, I should discontinue with the help of my clinician to ensure there are no negative reactions. I know my clinician may suggest I cut the dose or stop taking it altogether if certain medical conditions develop. This may happen if the side effects are severe or if there are health risks that cannot be controlled.

**MY SIGNATURE BELOW CONFIRMS THAT:**

- My clinician has talked with me about:
  - ▶ The benefits and risks of taking testosterone.
  - ▶ The possible or likely consequences of hormone therapy.
  - ▶ Potential alternative treatments.
- I understand the risks that may be involved.
- I know that the information in this form includes the known effects and risks. I also know that there may be unknown long-term effects or risks.
- I have had enough opportunity to discuss treatment options with my clinician.
- All of my questions have been answered to my satisfaction.
- I believe I know enough to take, refuse, or postpone testosterone therapy.
- I am 18 years old or older.

**BASED ON ALL THIS INFORMATION:**

- \_\_\_\_\_ I want to begin taking testosterone.
- \_\_\_\_\_ I do not wish to begin taking testosterone at this time.

\_\_\_\_\_  
*Patient's Signature*

\_\_\_\_\_  
*Date*

\_\_\_\_\_  
*Prescribing Physician's Signature*

\_\_\_\_\_  
*Date*

***Your health is important to us. If you have any questions or concerns, please come to sick call and an appointment with your PA/Physician will be made.***